UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,093	02/02/2004	Marcia K. Wolf	034047.033.4	6121

7590   11/13/2006

Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-JA (Ms. Elizabeth Arwine)
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER
GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<table>
<tr><td rowspan="2">Office Action Summary</td><td>Application No.
10/768,093</td><td>Applicant(s)
WOLF ET AL.</td><td></td></tr>
<tr><td>Examiner
Jennifer E. Graser</td><td>Art Unit
1645</td><td></td></tr>
</table>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _23 August 2006_.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _10,11,16-22,25,26 and 31_ is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _10,11,16-19 and 31_ is/are rejected.

7)☒ Claim(s) _20-22 and 26_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____ .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can

be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted on 8/23/06 is made.

Claims 10, 11, 16-22, 25, 26 and 31 are currently pending.

Claim Rejections - 35 USC § 103

1.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

2.   Claims 10, 11, 25 and 31 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Wolf et al (different inventive entity) (Submitted. Jan. 1994. UniProt

Accession # P53509).

Wolf et al disclose a protein which is 100% identical to Applicants' SEQ ID NO: 9.

The compositions of claims 11 and 25 only require the protein. However, the protein

disclosed by Wolf et al contains the N-terminal signal sequence so it is 18 amino acids

longer than that of Applicant's SEQ ID NO:9 which does not contain the signal

sequence. It was well known in the prior art at the time the invention was made that the

N-terminal, hydrophobic sequences which are mediate the attachment of newly

translated polypeptide chains to intracellular membranes in secretory proteins, such as

the one which is claimed, is cleaved off during expression. See

'http://crisp.cit.nih.gov/Thesaurus/00006706.htm'. The Wolf et al reference specifically

recites that amino acids 1-18 are the 'signal peptide'. Accordingly, it would have been

obvious to one of ordinary skill in the art at the time the invention was made that to

express the protein and achieve the protein minus the signal sequence, which would be

identical to SEQ ID NO:9. The recombinant expression methods known in the art were

well known at the time the invention was made.

Response to Applicant's Arguments:

Applicants argue that the claims have been limited to 'consisting of' and,

therefore, the protein disclosed by Wolf et al does not anticipate the claims. This

argument has been addressed in the rejection set forth above.

Claim Rejections - 35 USC § 102/103

3.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4.   Claims 10, 11, 16, 17, 18, 19, 25 and 31 are rejected under 35 U.S.C. 102(b) as

being anticipated by Wolf et al (1989, Infect.Immun. 57(1): 164-173) or, in the

alternative, under 35 U.S.C. 103(a) as obvious over by Wolf et al (1989, Infect.Immun.

57(1): 164-173).

Wolf et al. disclose compositions that comprise CS6 protein from *E.coli* E8775,

the same strain from which the protein of SEQ ID NO: 9 was isolated. One of the

disclosed compositions that comprised CS6 proteins was an agarose gel containing the

CS6 16 kDa band (Figure 3, a type of acceptable carrier). An additional composition

that comprised the W8775 CS6 protein was a saline extract of E8775 (see page 167,

col. 1, paragraph 1). The protein was used to generate antisera. Additionally, it was

shown that the whole cell bacterium raised antibodies against the CS6 protein. Wolf et

al do not disclose the amino acid sequence of E8775 16kDa protein CS6, but the amino

acid sequence of a protein is an inherent structural characteristic. Inherently the

reference anticipates the now claimed invention. Atlas Powder Co. V IRECA, 51

USPQZd 1943, (FED Cir. 1999) states Artisans of ordinary skill may not recognize the

inherent characteristics or functioning of the prior art...However, the discovery of a

previously unappreciated property of a prior art composition, or of a scientific

explanation for the prior arts functioning, does not render the old composition patentably

new to the discoverer. The Court further held that this same reasoning holds true when

it is not a property but an ingredient that is inherently contained in the prior art.

The disclosed protein of the prior art reference appears to be identical to

Applicants' protein given the identity of the source. Since the Patent Office does not

have the facilities for examining and comparing Applicant's BPIP with the BPIP of the

prior art, the burden of proof is upon applicants to show an unobvious distinction

between the material structural and functional characteristics of the claimed protein and

the protein of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

Response to Applicants' Arguments:

Applicants argue that Wolf et al does not teach the polypeptide because a

polypeptide similar to SEQ ID NO:9, such as #P533509, would be expected to result in

an eluted band in a gel in a position substantially similar to SEQ ID NO:9. They argue

that the protein of the diluted band could be easily mistaken for one or the other without

a suitable control and thus, it is unclear that the protein of the eluted band is SEQ ID

NO:9 rather than #p53509. They argue that Wolf et al does not disclose the sequence

of the eluted band used to generate the antisera. These arguments have been fully and

carefully considered but are not deemed persuasive.

Wolf et al do not disclose the amino acid sequence of E8775 16kDa protein CS6,

but the amino acid sequence of a protein is an inherent structural characteristic.

Inherently the reference anticipates the now claimed invention. Atlas Powder Co. V

IRECA, 51 USPQZd 1943, (FED Cir. 1999) states Artisans of ordinary skill may not

recognize the inherent characteristics or functioning of the prior art...However, the

discovery of a previously unappreciated property of a prior art composition, or of a

scientific explanation for the prior arts functioning, does not render the old composition

patentably new to the discoverer. The Court further held that this same reasoning holds

true when it is not a property but an ingredient that is inherently contained in the prior

art. Wolf et al. disclose compositions that comprise CS6 protein from *E.coli* E8775, the

same strain from which the protein of SEQ ID NO: 9 was isolated. One of the disclosed

compositions that comprised CS6 proteins was an agarose gel containing the CS6 16

kDa band (Figure 3, a type of acceptable carrier). An additional composition that

comprised the W8775 CS6 protein was a saline extract of E8775 (see page 167, col. 1,

paragraph 1). The protein was used to generate antisera. Additionally, it was shown

that the whole cell bacterium raised antibodies against the CS6 protein.

Applicants have not shown that the protein taught by Wolf et al does not elute in

a gel in a similar position to that of SEQ ID NO:9.

Claim Rejections - 35 USC § 112 2nd paragraph

5.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly
> claiming the subject matter which the applicant regards as his invention.

6.   Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite

for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

Claim 19 recites that the polypeptide is administered in the form of a 'host cell

that expresses the polypeptide and that the host cell is 'killed'. It is unclear how a killed

host cell and express the polypeptide. It does not appear that a killed host cell would

display the protein and, therefore, an antigenic response against the polypeptide would

not be generated. Clarification and/or correction is requested.

Claims 20-22 and 26 are objected to as being dependent upon a rejected base

claim.

7.   Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

8.   Correspondence regarding this application should be directed to Group Art Unit
1645. Papers related to this application may be submitted to Group 1600 by facsimile
transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in
Remsen. The faxing of such papers must conform with the notice published in the
Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is
571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Jennifer E. Graser whose telephone number is (571)
272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-
6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Bruce Campell, can be reached on (571) 272-0974.

Any inquiry of a general nature or relating to the status of this application should
be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser   11/11/06
Primary Examiner
Art Unit 1645

OM protein - protein search, using sw model

Copyright   GenCore version 5.1.7
Copyright (c) 1993 - 2006 Bioacceleration Ltd.

Run on: April 10, 2006, 10:13:49 ; Search time 230 Seconds
          (without alignments)
          417.182 Million cell updates/sec

Title: US-10-768-093-9
Perfect score: 699
Sequence: 1 RTBIATKNPPVSTTISKSPP..........EKKISPGIYNDQVMGYYVN 136

Scoring table: BLOSUM62
               Gapop 10.0 , Gapext 0.5

Searched: 2166443 seqs, 705528306 residues

Total number of hits satisfying chosen parameters: 2166443

Minimum DB seq length: 0
Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%
                 Maximum Match 100%
                 Listing first 45 summaries

Database : UniProt_05.80:*
            1: uniprot_sprot:*
            2: uniprot_trembl:*

'Pred. No. is the number of results predicted by chance to have a
score greater than or equal to the score of the result being printed,
and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match	Length	DB	ID		Description
1	699	100.0	154	1	F6A2_ECOLI	P53509	escherichia
2	655	93.7	154	1	F6A1_ECOLI	P53508	escherichia
3	120.5	17.2	167	1	F6B1_ECOLI	P53510	escherichia
4	113.5	16.2	167	1	F6B2_ECOLI	P53511	escherichia
5	92	13.2	440	2	Q54US8_DICDI	Q54us8	dictyosteli
6	87	12.4	918	2	Q72P30_LEPIC	Q72p30	leptospira
7	87	12.4	918	2	Q8F7D7_LEPIN	Q8f7d7	leptospira
8	83	11.9	749	2	Q81A3_BACCR	Q81a3	bacillus ce
9	83	11.9	12268	2	Q8MQ08_CAEEL	Q8mq08	caenorhabdi
10	83	11.9	13100	2	Q09165_CAEEL	Q09165	caenorhabdi
11	82	11.7	248	2	Q6HOE5_BACAN	Q6hqe5	bacillus an
12	82	11.7	248	2	Q630P3_BACCZ	Q630p3	bacillus ce
13	82	11.7	248	2	Q6HASB_BACHK	Q6has8	bacillus th
14	82	11.7	264	2	Q81JU4_BACAN	Q81ju4	bacillus an
15	82	11.7	268	2	Q4MGG1_BACCE	Q4mgg1	bacillus ce
16	82	11.7	279	2	Q84ZI4_9BACT	Q84zi4	uncultured
17	82	11.7	287	2	Q72X92_BACC1	Q72x92	bacillus ce
18	82	11.7	524	2	Q6CDU2_YARLI	Q6cdu2	yarrowia li
19	81.5	11.7	449	2	Q87IZ5_VIBPA	Q87iz5	vibrio para
20	81.5	11.7	454	2	Q897U6_CLOTE	Q897u6	clostridium
21	81.5	11.7	610	2	Q5WVI1_LEGPL	Q5wvi1	legionella
22	81.5	11.7	610	2	Q5X443_LEGPA	Q5x443	legionella
23	81.5	11.7	610	2	Q5ZUD2_LEGPH	Q5zud2	legionella
24	81	11.6	318	2	Q4KIL8_STRPN	Q4kil8	streptococc
25	81	11.6	318	2	Q4KLQ5_STRPN	Q4klq5	streptococc
26	81	11.6	595	2	Q8YVL1_ANASP	Q8yvl1	anabaena sp
27	81	11.6	1047	2	Q9RB35_9SPHI	Q9rb35	cytophage s
28	81	11.6	1838	2	O88207_MOUSE	O88207	mus musculu
29	80.5	11.5	360	1	AROC_HAEDU	AROC_HAEDU	haemophilus
30	80.5	11.5	1303	2	Q4WIH6_ASPFU	Q4wih6	aspergillus
31	80	11.4	251	2	Q814R6_BACCR	Q814r6	bacillus ce
32	80	11.4	279	2	Q84219_9BACT	Q84219	uncultured
33	80	11.4	316	2	Q523KO_MAGGR	Q523ko	magnaporthe
34	80	11.4	440	2	Q8A503_BACTN	Q8a503	bacteroides
35	80	11.4	1936	2	Q4QDF6_LEIMA	Q4qdf6	leishmania
36	79.5	11.4	385	2	Q7RKR4_PLAYO	Q7rkr4	plasmodium
37	79.5	11.4	459	2	Q8D3R5_VIBVU	Q8d3r5	vibrio vuln
38	79.5	11.4	826	2	Q8DX37_STRA5	Q8dx37	streptococc
39	79	11.3	1372	2	Q5PB95_ANAMM	Q5pb95	anaplasma m
40	79	11.3	1840	2	Q9JI03_RAT	Q9ji03	rattus norv
41	78.5	11.2	279	2	Q5K2B9_9BACT	Q5k2b9	uncultured
42	78.5	11.2	279	2	Q5K2P1_9BACT	Q5k2p1	uncultured
43	78.5	11.2	279	2	Q5K2F7_9BACT	Q5k2f7	uncultured
44	78.5	11.2	279	2	Q5K2F9_9BACT	Q5k2f9	uncultured
45	78.5	11.2	279	2	Q5K2H9_9BACT	Q5k2h9	uncultured

[handwritten annotation: "Wolf et al. ALIGNMENTS Submitted 1/94"]

RESULT 1
F6A2_ECOLI
ID   F6A2_ECOLI   STANDARD;   PRT;   154 AA.
AC   P53509;
DT   01-OCT-1996 (Rel. 34, Created)
DT   01-OCT-1996 (Rel. 34, Last sequence update)
DT   10-MAY-2005 (Rel. 47, Last annotation update)
DE   CS6 fimbrial subunit A precursor (CS6 pilin).
GN   Name=cssA;
OS   Escherichia coli.
OC   Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacteriales;
OC   Enterobacteriaceae; Escherichia.
OX   NCBI_TaxID=562;
RN   [1]
RP   NUCLEOTIDE SEQUENCE.
RC   STRAIN=B8775;
RA   Wolf M.K., de Haan L.A.M., Cassels P.C., Willshaw G.A., Gestel B.C.M.,
RA   Gaastra W., Warren R., Boedeker B.C.;
RL   Submitted (JAN-1994) to the EMBL/GenBank/DDBJ databases.
-!- FUNCTION: Fimbriae (also called pili), polar filaments radiating
CC   from the surface of the bacterium to a length of 0.5-1.5
CC   micrometers and numbering 100-300 per cell, enable bacteria to
CC   colonize the epithelium of specific host organs.
CC
CC   This Swiss-Prot entry is copyright. It is produced through a collaboration
CC   between the Swiss Institute of Bioinformatics and the EMBL outstation -
CC   the European Bioinformatics Institute. There are no restrictions on its
CC   use as long as its content is in no way modified and this statement is not
CC   removed.
CC
DR   EMBL; U04846; AAB51361.1; -; Unassigned_DNA.
KW   Fimbria; Signal.
FT   SIGNAL   1   18   Potential.
FT   CHAIN   19   154   CS6 fimbrial subunit A.
SQ   SEQUENCE   154 AA; 16940 MW; 421B223D9FA5FCB8 CRC64;

Query Match   100.0%; Score 699; DB 1; Length 154;
Best Local Similarity   100.0%; Pred. No. 1.2e-56;
Matches 136; Mismatches   0; Conservative   0; Indels   0; Gaps   0;

Qy   1 RTBIATKNPPVSTTISKSPPAPEPRIQPSPGENVGKEGALLPSVNLTVPENVSQVTTVPPV 60
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   19 RTBIATKNPPVSTTISKSPPAPEPRIQPSPGENVGKEGALLPSVNLTVPENVSQVTTVPPV 78

Qy   61 YDBDYGLGRLVNTADASQSIIYQIVDBKGKQMLKDHGABVTPNQITPKALNYTSGEKKI 120
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   79 YDBDYGLGRLVNTADASQSIIYQIVDBKGKQMLKDHGABVTPNQITPKALNYTSGEKKI 138

Qy   121 SPGIYNDQVMGYYVN (136)
             |||||||||||||||
Db   139 SPGIYNDQVMGYYVN 154

RESULT 2